IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Group Art Unit: 1615
ERNING XIA et al. : Examiner: BETHANY P. BARHAM
Serial No. 10/725,159
Filed: December 1, 2003
For: GENTLE AND ENHANCED PRESERVATIVE SYSTEMS
Attorney Docket No. P03366

AMENDED BRIEF ON APPEAL

HONORABLE COMMISSIONER OF PATENTS
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Sir:

In accordance with 37 C.F.R. § 41.37, Appellants filed an appeal brief on July 17, 2008. Appellants received a Notification of Non-Compliant Appeal Brief dated July 31, 2008 because Appellants' appeal brief does not contain certain sections. In response to this Notification, Appellants are submitting this amended brief to cure the defects noted in the Notification. Although the Notification indicates that the entire brief is not required to be submitted in response to the Notification, Appellants are submitting the entire amended brief in order to facilitate the review by the Board.

I. Real Party in Interest

The real party in interest for the above-identified patent application is Bausch & Lomb Incorporated, the employer of the inventors named in the present invention. The named inventors have assigned their entire right, title, and interest in the present invention to Bausch & Lomb Incorporated.

II. Related Appeals And Interferences

There are no prior and pending appeals, interferences or judicial proceedings known to Appellants, Appellants' legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the instant appeal.

III. Status of the Claims

Claims 1-3, 5-6, 8, and 13-19 were canceled.

Claims 4, 7, 9-12, 20 and 21 are pending and are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hu et al. (U.S. Patent 6,274,133; hereinafter "Hu") in view of Sugiura (U.S. Patent 5,928,606).

Claims 4, 7, 9-12, 20 and 21 are being appealed.

IV. Status of Amendments

Appellants filed a response to the final Office action, without amending the claims, dated April 25, 2008, two months after the date of the final Office action. In that response, Appellants respectfully presented arguments that a combination of Hu and Sugiura does not teach or suggest all of the limitations of each of the pending claims, and thus, the claims are patentable over Hu and Sugiura under 35 U.S.C. § 103(a). In the Advisory action dated May 9, 2008, the Examiner maintained the rejection of the claims because, among other things, she still failed to see or acknowledge the difference between a wetting agent, which is taught by the prior art, and a preservative, which is claimed in the pending claims.

V. Summary of the Claimed Subject Matter

The claims in the present appeal consist of two independent claims (claims 20 and 21) and six dependent claims (claims 4, 7, and 9-12).

1) Independent claim 20 recites a method of imparting a preservative efficacy to a contact lens solution, which method comprises providing in said contact lens solution one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in combination with one or more polyquaternium-10 cationic

polysaccharides, wherein the saccharides and cationic polysaccharides are in amounts effective for solution preservation.

The combination of a saccharide and a cationic polysaccharide is disclosed, for example, in paragraph 0006 of the original specification (page 3, lines 16-17). Saccharides in D or L forms are disclosed, for example, in paragraph 0017 of the original specification (page 6, line 9). Glucose and α-methyl gluco-pyranoside (in D form) are disclosed in paragraph 0017 of the original specification (page 6, lines 10-11). Amounts of saccharides are disclosed, for example, in paragraph 0017 of the original specification (page 6, lines 12-15). Cationic polysaccharides are disclosed, for example, in paragraph 0018 of the original specification (page 6, lines 16-17). Polyquaternium-10 and variations thereof are disclosed, for example, in paragraph 0020 of the original specification (page 8, lines 6-8). Amounts of cationic polysaccharides are disclosed, for example, in paragraph 0020 of the original specification (page 8, lines 2-6). Combinations of glucose and/or α-methyl gluco-pyranoside and a polyquaternium-10 (Polymer JR) are disclosed, for example, in Table 6 of the original specification (page 23, lines 13-14), Table 12 (page 35, lines 13-14). The use of compositions containing a saccharide and a cationic polysaccharide for preserving contact lens solutions along with amounts for solution preservation are disclosed, for example, in paragraph 0042 of the original specification (page 39, lines 1-14).

2) Independent claim 21 recites a method of imparting a preservative efficacy to a solution that is usable for treating a medical device, which method comprises providing in said solution one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in combination with one or more polyquaternium-10 cationic polysaccharides, wherein the saccharides and cationic polysaccharides are in amounts effective for solution preservation.

The use of a composition of the present invention for preserving a solution for treating a medical device is disclosed, for example, in paragraph 0018 (page 6, line16 through page 7, line 1). Examples of disclosure of other elements of claims 21 are also as stated above. For conciseness, they are not enumerated here again.

VI. Grounds of Rejection to Be Reviewed on Appeal

The only ground of rejection that must be reviewed in this appeal is whether claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura.

VII. The Argument

Issue -- Whether 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura.

Claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura because a combination of Hu and Sugiura does not teach or suggest all the elements of each of claims 4, 7, 9-12, 20 and 21.

Obviousness requires a suggestion of all the elements in a claim and a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Ex parte Alexander*, 86 U.S.P.Q.2d 1120, 1122 (BPAI, Nov. 30, 2007) (quoting *CFMT, Inc. V. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007)) (emphasis added). It is fatal to the rejection when "the Examiner has not identified all the elements of [a] claim [or] provided a reason that would prompted the skilled worker to have arranged them in the manner necessary to reach the claimed invention." *Id.*

Here, each of claims 4, 7, 9-12, 20, and 21 recites a method of imparting preservative efficacy to a solution or an ophthalmic solution by providing in the solution one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in combination with one or more polyquaternium-10 cationic polysaccharides, wherein the saccharides and cationic polysaccharides are in amounts effective for solution preservation. Nowhere in the combined disclosure of Hu and Sugiura Patent is found such a combination of the recited ingredients together, present in amounts effective for solution preservation. The Examiner has ignored this element of each of the claims. Moreover, the Examiner has not offered any rationale that the use of mono or disaccharides or ethoxylated glucose (Hu, claim 5) as wetting agents and cationic cellulosic polymers (Hu, column 5, lines 13-16) as inhibitors of lipid deposition on contact lens surface would be the same as a combination of glucose or α-methyl gluco-pyranoside and polyquaternium-10 effective as preservative, as recited in the pending claims. Nor has the Examiner offered any rationale why such wetting agents and inhibitors of lipid deposition of

Hu may be combined with the use of glucose or mannitol as tonicity agents in Sugiura (see; e.g., Sugiura, column 10, lines 48-51) to arrive at a combination of glucose or α-methyl gluco-pyranoside and polyquaternium-10 effective as preservative, as recited in the pending claims.

As the Supreme Court admonished in *KSR Int'l Co.*, 127 S.Ct. at 1741, "a patent composed of several elements is not proved obvious merely by demonstrating that each element [note that "element" means limitation of the claims, not merely physical ingredient] was, independently, known in the prior art. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does." (Emphasis added.) Here, the Examiner has not articulated any reason why a person of ordinary skill would use a wetting agent, an inhibitor of lipid deposition, and a tonicity agent (the prior art) as a preservative (the claimed invention).

Since a combination of Hu and Sugiura does not teach or suggest that glucose or α-methyl gluco-pyranoside and polyquaternium-10 as preservative and since the Examiner has not set forth any rationale why the taught wetting agents, inhibitors of lipid deposition, and tonicity agents would be used as preservative, claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura.

In addition, the Examiner has misunderstood the teaching of the prior art. The Examiner asserted that Hu discloses saccharides as suitable wetting agents (in claim 5 of this patent) and that Sugiura teaches the wetting agents including saccharides such as glucose (Office action dated February 25, 2008 (hereinafter "Office action"), page 3, citing col. 10, lines 36-52 of the '606 Patent). First of all, the Examiner's latter assertion is not even correct. Sugiura, at the section cited by the Examiner, does not teach that saccharides were wetting agents. Instead, Sugiura teaches that saccharides were examples of tonicity agents. People of ordinary skill in the art understand that tonicity agents are not generally or necessarily wetting agents. Moreover, the Examiner has not set forth the reason why she considered tonicity agents to be preservatives. Tonicity agents are compounds that are used to adjust the osmolality of a solution (most often are inorganic salts, glycerine, or some limited monosaccharides). On the other hand, preservatives are compounds that prevent the growth of microorganisms.

The Appellants did not argue that Hu and Sugiura do not disclose wetting agents. Nor did the Appellants argue against each cited patent separately. Instead, the Appellants argued that the combination of these patents does not disclose all the elements of each of the claims (i.e., including the combination used as preservative). Specifically, the combination of these patents does not teach that the recited ingredients are included in a composition of the claims in amounts effective for solution preservation. The Examiner has not pointed to any part of the cited patents as proof of disclosure of such claimed limitation. Nor did the Examiner explain on the record why the teaching of separate wetting agents amounts to the teaching of the same compounds in combination with polyquaternium-10 in quantities effective as preservatives. When there is no teaching that a prior-art element would be useful in the claimed system, and a fair reading of the combined prior art disclosures teaches only the system of one of the references, the Examiner's strained consideration of these combined teachings would be a hindsight reconstruction of Appellants' claimed invention. *Ex parte van Ostrand*, BPAI, January 30, 2008.

Regarding the pending dependent claims, since a combination of the cited patents does not teach or suggest the combination of a cationic polysaccharide and one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in amounts effective for solution preservation, as recited in each of independent claims 20 and 21, pointing out that the cited prior art also discloses disparately other ingredients recited in dependent claims 4, 7, and 9-12 still does not cure the deficiency of the 103(a) rejection.

Moreover, claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura because a person of ordinary skill would not be expected to use a sugar as preservative to inhibit the growth of microorganisms.

At least some degree of predictability that the combination or modification would be successful is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (Fed. Cir. 1976).

It is known that microorganisms need a source of energy and moisture to grow. Sugars, including glucose or derivatives thereof, are known to be good sources of energy for microorganisms (as evidenced by the fact that agar has been used routinely for bacterial

culture). Thus, a person of ordinary skill would not have used glucose in an aqueous solution as part of a preservative. However, the Appellants proceeded against the conventional wisdom and demonstrated that a combination of glucose or α-methyl gluco-pyranoside and polyquaternium-10 (a derivative of cellulose, another sugar derivative) provided good preservative efficacy for the solution. See the microorganism inhibition results of the present solutions in Examples 6-9 and 12-13.

Since a person of ordinary skill does not expect success in using glucose as an ingredient of a preservative system for a solution, claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura.

In addition, the Appellants respectfully traverse the Examiner's reading that Sugiura's discussion of disinfection amounts to the same as preservation. Sugiura listed the following disinfectants, which are all non-sugar materials: polyhexamethylene biguanide hydrochloride salt (PHMB), a solution of chlorhexidine having a guanidine group, benzalkonium chloride, benzethonium chloride (Sugiura, column 6, lines 20-23), quaternary ammonium salts, guanidine, guanidine disinfectant in which a coupling group is introduced, such as: chlorhexidine, or chlorhexidine in which the coupling group is introduced; 1,17-diguanidino-9-aza-heptadecane, or 1,17-diguanidino-9-aza-heptadecane in which the coupling group is introduced; and polyhexamethylene biguanide, or polyhexamethylene biguanide in which the coupling group is introduced (Sugiura, column 6, lines 57-67). First, these are non-sugar materials. Second, the capacity and requirement for disinfection is not the same as those for preservation. Concentrations of these materials for disinfection would be much higher than those for preservation and would not be comfortable for the user's eyes. Thus, without a teaching or suggestion or a reason of why a discussion of non-sugar materials may be extended to sugar and sugar derivatives, even using knowledge available to a person of ordinary skill, Sugiura's materials cannot form a basis for a Section 103(a) rejection of the claimed method.

Regarding the Examiner's citation of U.S. Patent 6,916,958 as of interest (Office action dated February 25, 2008), the cited polyquaternium compounds are aminobiguanides, and not cationic polysaccharides recited in the claims presently on appeal. Thus, U.S. Patent 6,916,958 is not relevant to the issue at hand.

For the reasons set forth above, Appellants respectfully submit that claims 4, 7, 9-12, 20 and 21 are patentable and should be allowed. Appellants respectfully request that the Honorable Board of Patent Appeals and Interferences reverse the Examiner's final rejection and hold claims 4, 7, 9-12, 20 and 21 allowable.

VIII. Claim Appendix

The Claims on Appeal:

Claim 4 (Previously Presented): The method of claim 20, wherein said one or more cationic polysaccharides are selected from the group consisting of polyquarternium-10.

Claim 7 (Previously Presented): The method of claim 21, wherein said one or more cationic polysaccharides are selected from the group consisting of polyquarternium-10.

Claim 9 (Previously Presented): The method of claim 20 or 21 wherein said solution includes one or more buffers or buffering systems.

Claim 10 (Previously Presented): The method of claim 20 or 21 wherein said solution includes one or more tonicity agents.

Claim 11 (Previously Presented): The method of claim 20 or 21 wherein said solution includes one or more surfactants.

Claim 12 (Previously Presented): The method of claim 20 or 21 wherein said solution includes one or more viscosity agents.

Claim 20 (Previously Presented): A method of imparting a preservative efficacy to a contact lens solution, the method comprising:

providing in said contact lens solution a preserving agent that comprises one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in combination with one or more polyquaternium-10 cationic polysaccharides, wherein the saccharides and cationic polysaccharides are in amounts effective for solution preservation.

Claim 21 (Previously Presented): A method of imparting a preservative efficacy to a solution that is usable for treating a medical device, the method comprising:

providing in said solution a preserving agent that comprises one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in combination with one or more polyquaternium-10 cationic polysaccharides, wherein the saccharides and cationic polysaccharides are in amounts effective for solution preservation.

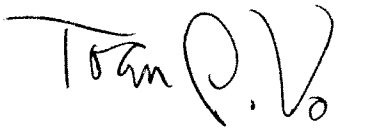
IX. Evidence Appendix

None

X. Related Proceeding Appendix

None

Respectfully submitted



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